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Example 1 of the '939 patent. In the parent application (also directed to product claims), it was explicitly stated that the primary basis for the rejection over the '939 patent was to be found in Example 1 of the '939 patent. Applicants would appreciate it if the Examiner would indicate if Applicants are incorrect in their assumption regarding the reliance of the present rejection on Example 1 of the '939 patent. Accordingly, given the length of the cited '939 patent, Applicants will focus their comments on Example 1 of the '939 patent.

The Final Action states that "it is the Examiner's position that the product egg of Cox et al. [reads] on the instant product claims." (Final Action, page 3, lines 12-13). The Examiner further states that the "temperature and time treatment used in Cox et al. (internal temperature of 54.4 C for 45 minutes) is at least enough to accomplish what Applicants were able to accomplish regarding the extent of Salmonella kill called for in the instant claims (see Table 2, page 16 and 17, first paragraph)." (Final Action, page 3, final 4 lines). It is further contended that:

Whether or not Cox et al. was aware of the product produced, the egg product of Cox et al. falls within the claim limitations as set forth, absent a showing to the contrary. The recitation of a newly discovered function or property (or in the instant case, perhaps, degree of pasteurization effected) inherently possessed by the prior art does not cause a claim drawn to such new function or property to distinguish over the prior art. Where the Patent Office has reason to believe that limitations asserted to be critical for establishing novelty may, in fact, be inherent characteristics of the prior art, it possesses authority to require applicant to prove that the product of the prior art does not possess such characteristics relied on. In re Swinehard, 169 USPQ 226.

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(Final Action, page 5, lines 5-13).

This rejection will be addressed below.

A. Legal standards for anticipation.

Anticipation requires that each and every element of the claim is found in a single prior art reference. *W. L. Gore & Associates Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Stated another way, all material elements of a claim must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. See *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

In some circumstances, an element may not be expressly disclosed by the prior art reference, but may be inherent in the disclosure. The Court of Appeals for the Federal Circuit has relatively recently set forth the Examiner's burden in establishing a *prima facie* case of inherency as a two-part test. *In re Robertson*, 169 F.3d 743; 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999).

Specifically, the Court stated:

If a particular prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized

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by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d at 745, 49 U.S. P.Q.2d at 1950-51; *emphasis added, quotation and citations omitted*. Thus, under the *Robertson* test, the Examiner has the burden of providing extrinsic evidence establishing that (1) the alleged inherent feature is "necessarily present in the thing described in the reference", and (2) "it would be so recognized by persons of ordinary skill." The *Robertson* Court described these as "critical principles" informing the inherency inquiry. *In re Robertson*, 169 F.3d at 745, 49 U.S. P.Q.2d at 1950-51.

The Federal Circuit and its predecessor court, the Court of Claims and Patent Appeals, have addressed the standard to support a rejection on the basis of inherency on previous occasions as well. For example, in *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 20 U.S.P.Q.2d 1746 (Fed. Cir. 1991), the Federal Circuit stated:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. . . . Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. This modest

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flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologist is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.

Continental Can Co., 948 F.2d at 1268-69, 20 U.S.P.Q.2d at 1749-50; *emphasis added, citations omitted*; see also *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 34 U.S.P.Q.2d 1565 (Fed. Cir. 1995), "The disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art." *Glaxo Inc.*, 52 F.3d at 1047, 34 U.S.P.Q.2d at 1567).

Further, in *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323 (C.C.P.A. 1981), it is stated that inherency may be found if the "disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient." *In re Oelrich*, 666 F.2d at 581, 212 U.S.P.Q. at 326; *emphasis added*. Finally, as Applicants have previously noted, the United States Supreme Court has stated that "[a]ccidental results, not intended and not appreciated, do not constitute anticipation." *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923)(*emphasis added*).

As discussed in more detail below, it is the Applicants' position that the rejection in the Final Action does not satisfy the burden for establishing anticipation by the '939 patent, either expressly or inherently, under § 102 (e).

B. The Present Invention is Novel over the '939 Patent.

The present claims are drawn to thermally treated shell eggs that "received a thermal treatment sufficient to cause at least about a 5D reduction in *Salmonella enteritidis* in the albumen and in the yolk of said shell egg but

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insufficient to cause more than insignificant coagulation of the albumen and the yolk of said shell egg." The claimed invention is not to be found, expressly or inherently, in the '939 patent. In particular, the claimed invention is not anticipated by Example 1 of the '939 patent. In contrast to the teachings of the '939 patent, Applicants have employed thermal treatments with intact shell eggs to reduce levels of *Salmonella* therein by at least 5D, at conditions previously thought insufficient to achieve the recited levels of *Salmonella* kill, without unduly impairing egg quality and function.

The Examiner states that the '939 patent discloses the presently-claimed thermally-treated shell eggs. Applicants respectfully disagree. Specifically referring to Example 1 of the '939 patent, this Example discloses a time-temperature curve for bringing the internal contents of a shell egg up to a target temperature for pasteurization. This Example does not disclose (either expressly or inherently) or enable one skilled in the art to produce the presently-claimed shell eggs.

More specifically, Example 1 of the '939 patent discloses a time-temperature study in which intact shell eggs were heated in a peanut oil bath preheated to 57° C (134.6° F). The internal temperature of the eggs was monitored at 5-minute intervals. This study found that eggs heated at 57° C for a time between 40 and 45 minutes reached the internal target temperature of 54.4° C (129.9°F) and showed a thickening of the white. This study further found that eggs heated for 1.5 hours at 57° C exhibited similar functionality to eggs heated at 59.4° C for 1.25 hours.

Thus, Example 1 of the '939 patent does not disclose heating a shell egg at an internal temperature of 54.4°C (129.9°F) for 45 minutes. Example 1 of the '939 patent teaches that it takes from between 40 and 45 minutes for the internal contents of the egg at a starting temperature of 4.4°C (40°F) to reach the target temperature of 54.4°C (129.9°F) when heated in a 57°C (134.6°F) peanut oil bath. In other words, the shell egg is heated for 40 to 45 minutes to reach an internal temperature of 54.4°C, but is not held for 40 to 45 minutes at this internal temperature.

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Assuming the Examiner is relying on Example 1 of the '939 patent, Applicants respectfully submit that the Examiner has misconstrued the teachings of this example. The Applicants further submit that the Final Action has erroneously equated the shell egg of Example 1 of the '939 patent that has been heated at 57°C (134.6°F) for 40 to 45 minutes to achieve an internal target temperature of 54.4°C (129.9°F) with the shell eggs described in Table 2 of the present application.

As shown in Figure 2 of the present application, the eggs described in Table 2 started off at an internal temperature of about 23 or 24 °C. In contrast, the eggs described in Example 1 of the '939 application had a starting internal temperature of 4.4°C. Accordingly, the times and temperatures in Example 1 of the '939 patent cannot be directly compared with the times and temperatures in Table 2 of the present application. In Example 1 of the '939 patent, 40 to 45 minutes at 57°C was only sufficient to bring the egg up to the internal target temperature of 54.4°C. It would not be sufficient to produce a shell egg having at least a 5-log reduction in *Salmonella*, as presently claimed.

As Indicated in Table 2 of Schuman et al., (1997) *J. Applied Microbiology* 83:438, (copy enclosed), shell eggs having a mean internal starting temperature of 21.1 and 19.6 °C, exhibited only a 2.0-2.5 log reduction in viable *Salmonella enteritidis* populations during the 35 minute "come up" time in a 57°C waterbath (see Schuman et al., page 441, Col. 2, lines 3-5). A shell egg having an internal starting temperature of only 4.4°C, as described in Example 1 of the '939 patent, would have a much lower reduction in *Salmonella* population within the egg. Clearly, the shell egg described in Example 1 of the '939 patent would have significantly less than a 5-log reduction in *Salmonella* therein.

In sum, the shell egg disclosed by Example 1 of the '939 patent, which has been heated in a 57°C peanut oil bath for 40-45 minutes from a starting temperature of 4.4°C, does not anticipate the present invention, either expressly or inherently. The shell egg in Example 1 of the '939 patent would

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not have the claimed reductions in *Salmonella*. Thus, the disclosure of the '939 patent upon which the Final Rejection is based (*i.e.*, a shell egg heated at 45 minutes in a 57°C waterbath to reach an internal target temperature of 54.4°C) does not anticipate the present rejection.

In addition, Applicants submit that one of ordinary skill in the art at the time of invention would not have viewed Example 1 of the '939 patent as having disclosed or suggested the presently-claimed shell eggs having at least a 5-log reduction in *Salmonella*.

Furthermore, in Example 1 of the '939 patent there was no attempt to ascertain microorganism levels, much less *Salmonella*, within the heat-treated eggs (See the **Supplemental Ball Declaration submitted with Applicants' response of February 25, 2002, para. 3**). Likewise, Example 1 does not evaluate whether there is a reduction in microbial populations in the shell egg as a result of the heating process. Any reduction in *Salmonella* population in the shell eggs described in Example 1 of the '939 patent would not have been appreciated by one of ordinary skill in the art by reading the '939 disclosure. Applicants further submit that similar problems are present in the other examples of the '939 patent. See *e.g.*, the **Supplemental Ball Declaration, para. 3-6**, (indicating that the studies described in Example 3 of the '939 patent do not provide any meaningful data on the effects of thermal treatment on microbial kill in intact eggs).

Thus, the examples of the '939 patent do not teach and enable the presently-claimed shell eggs. Any reduction in *Salmonella* population in the shell eggs described in the examples of the '939 patent would not have been appreciated by one of ordinary skill in the art by reading the '939 disclosure. Indeed, in view of the '939 reference when taken as a whole and the state of the art, one of ordinary skill would not have viewed the '939 patent as teaching or enabling a shell egg having at least a 5-log reduction in *Salmonella*, as presently claimed.

For example, Figure 10 of the '939 patent teaches that the time and temperature conditions used in the examples of that '939 patent are not

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effective for pasteurization. Figure 10 of the '939 patent teaches that thermal treatments at or above the *Salmonella* destruction curve ("Expected *Salmonella*" line of Figure 1 of the present application) must be applied to pasteurize shell eggs. Cox et al. did not realize that less severe thermal treatments could be employed prior to filing the previously-cited continuation-in-part application (U.S. Patent No. 5,589,211). As described in the present application (at page 6, lines 23-26), the treatments indicated by Figure 10 are likely to result in coagulation or other losses in functionality in the treated shell egg (see the **Supplemental Ball Declaration, para. 7**). Significantly, Figure 10 was omitted from the Cox et al. CIP application.

The Final Action states that there may be other reasons why Figure 10 was omitted from the CIP application. Nonetheless, the inclusion of Figure 10 in the '939 patent is significant because the '939 patent must be assessed as a whole for what it fairly teaches one of ordinary skill in the art. As discussed above, Figure 10 would teach one of ordinary skill in the art that pasteurization was not achieved in the examples of the '939 patent.

Moreover, as discussed in the Amendment submitted February 25, 2002, the Van Lith et al., Stadelman et al., and Hou et al. references (items 51, 59 and 61 on the PTO-1449 form submitted August 6, 2001) indicate that as recently as 1996, the state of the art suggested that the thermal treatments of the invention are not effective to produce a pasteurized shell egg. Accordingly, one of ordinary skill in the art in considering the experiments described in, for example, Examples 1 and 3 of the '939 patent would find no disclosure or suggestion therein, either expressly or inherently, that Cox et al. achieved a pasteurized shell egg having at least a 5-log reduction in *Salmonella* as presently claimed.

The Examiner states in the Final Action at page 4 (lines 6-20) that

Hou does set forth that prior art treatment in a water bath at 57 C for greater than 30 minutes "often resulted in denatured egg white proteins." However, this does not mean that the egg white has denatured in every case (but only "often");

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moreover, this does not provide any information as to what point actual coagulation of the egg white occurs.

Applicants respectfully submit that the Examiner is expressly attempting to use hindsight to construe the language of Hou et al. so as to support the present rejection. The relevant perspective is that of one of ordinary skill in the art considering the reference as a whole. The unambiguous language of Hou et al. states that: "The use of a 57 °C water-bath gave a maximum temperature increase without protein denaturation for up to 30 min." (sentence spanning pages 97-98). In addition, Hou et al. concludes that: "Therefore, the maximum allowable destruction of *S. enteritidis* ATCC 13076 in shell eggs by water-bath heating without egg white denaturation was approximately 3 logs (Fig 1.) (page 98, Col. 1, lines 6-10; emphasis added).

The Examiner further states that "Van Lith et al. indicates that egg white coagulation is effected when heating at the combination of above 57 C and 20 minutes, it does not set forth at what point above 57 C and 20 minutes this actually occurs (e.g., 58C and 24 minutes?)". Applicants again respectfully submit that the Van Lith et al. reference is unambiguous that pasteurization by immersion is ineffective to achieve the recited levels of reduction in *Salmonella enteritidis* in shell eggs. Specifically, Van Lith et al. state: "From the calculated internal temperatures, it could already be expected, that this heat treatment in water [at 57° C] never could be effective to destroy *Salmonella* bacteria if present." (page 159, Col. 1, paragraph 5; emphasis added). Moreover, this reference forcefully concludes: "As the albumen coagulates strongly already at the temperature and time combination above 57°C and 20 minutes, no beneficial effect from higher temperatures of longer times can be expected." (page 159, Col. 1, paragraph 8; emphasis added).

In sum, Applicants submit that the Hou et al., Van Lith et al., and Stadelman references, when considered as a whole, would clearly and unambiguously teach one of ordinary skill in the art away from the use of the

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thermal treatments of the present invention to achieve the recited reductions in *Salmonella enteritidis* in a shell egg.

Applicants further submit that the '939 patent fails to enable one skilled in the art to produce a pasteurized shell egg according to the present claims. The '939 patent, and more specifically Example 1 of the '939 patent, simply does not teach pasteurization of a shell without significant coagulation to one skilled in the art. Even if, *arguendo*, a pasteurized shell egg was achieved in the '939 patent, this effect would have been completely accidental and unappreciated. The '939 patent would not teach one skilled in the art to make and use the presently-claimed invention.

Thus, in addition to the reasons set forth above, the '939 patent does not anticipate the present invention because it does not enable one skilled in the art to make and use the claimed shell eggs. See MPEP § 2121.01; *In re Donohue*, 226 USPQ 619 (Fed. Cir. 1985); *In re Hoeksema*, 158 USPQ 596 (CCPA 1968).

C. The '939 patent does not inherently anticipate the present invention.

As discussed at length in the previous section, the '939 patent, and more specifically Example 1 of the '939 patent, does not disclose or suggest a shell egg within the scope of the present claims. Moreover, the present rejection over the '939 patent does not satisfy the legal standards for inherency, which are set forth above.

The rejection in the Final Action on the basis that Cox et al. inherently discloses the present invention is deficient in that the '939 patent does not "show" to one of ordinary skill in the art that the claimed thermally pasteurized egg would be "the natural result" of the time-temperature curves in the cited examples of the '939 patent. See *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Under the *Robertson* test, the Examiner has failed both to (1) provide extrinsic evidence demonstrating that the claimed shell egg would necessarily flow from the time-temperature studies of

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the '939 patent (for example, the studies of Example 1 of the '939 patent), and (2) show that one skilled in the art would immediately so recognize. The instant case is not one where "modest flexibility in the rule" that each and every claim element must be disclosed by the cited reference is appropriate. See *Continental Can, Co. vs. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2d 1746, 1749-50 (Fed. Cir. 1991). Likewise, the '939 patent does not represent a situation in which "the common knowledge of the technologist is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." *Id.*

The Examiner cites dicta from *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226 (C.C.P.A. 1971) for the proposition that "[w]here the Patent Office has reason to believe that limitations asserted to be critical for establishing novelty may, in fact, be inherent characteristics of the prior art, it possesses authority to require applicant to prove that the product of the prior art does not possess such characteristic relied on." (Final Action, page 5, lines 9-13). However, the Examiner does not respond to the controlling authority from the United States Supreme Court that holds that "accidental results" that are "not appreciated" cannot be the basis of anticipation. See *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923).

Applicants respectfully submit that the outstanding rejection does not set forth a *prima facie* case of inherency. Applicants further assert that in the absence of a *prima facie* case, Applicants are not required to prove that the '939 patent did not achieve a pasteurized shell egg as presently claimed. Nonetheless, as Applicants have discussed in the previous section, the example from the '939 patent relied upon in the Final Action (*i.e.*, a shell egg heated for 45 minutes in a 57°C bath to reach an internal temperature of 54.4°C) has been distinguished from the presently-claimed egg in that the heated shell egg of Example 1 of the '939 patent does not achieve a shell egg having at least a 5-log reduction in *Salmonella*, as presently claimed.

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The Applicants are aware that one may not attempt to claim a prior art composition on the basis of a newly-found characteristic or property thereof. The present rejection may be readily distinguished from this situation.

The '939 patent does not disclose a prior art composition or product for which Applicants have merely discovered a new property or use. The '939 patent does not disclose the claimed pasteurized shell egg having at least a 5D reduction in *S. enteritidis* therein. **Applicants have discovered the claimed product itself, not merely a new characteristic or use thereof.**

The cited examples in the '939 patent simply carried out routine time-temperature studies for shell eggs placed within a water or oil bath. The purpose of these experiments is not stated in the '939 patent, but it appears to be a preliminary evaluation of the "come up" time to heat the internal contents of the egg to a target temperature. The '939 patent does not disclose or suggest to one of ordinary skill that any reduction in *S. enteritidis* was achieved, and certainly does not disclose or suggest the claimed reductions in *S. enteritidis*.

Accordingly, Applicants submit that one of ordinary skill in the art would **not have the slightest hint** that one of the particular time points in Example 1 of the '939 patent might correspond to an effective thermal treatment to for pasteurizing a shell egg by achieving the recited reductions in *Salmonella* without significant coagulation, as presently claimed. The presently-claimed invention can only be found within In Cox et al. (in particular, Example 1 of Cos et al.), if at all, through the impermissible use of hindsight. Without using the present application as a guide, one of ordinary skill in the art would have no inkling as to an effective thermal treatment for pasteurizing a shell egg without significant coagulation thereof, as is presently claimed.

In fact, the Van Lith et al., Stadelman et al., and Hou et al. references, discussed above, clearly indicate that those skilled in the art did not appreciate the claimed invention as recently as 1996.

The Examiner states that it is irrelevant whether Cox et al. did or did not appreciate whether or not a pasteurized egg was produced by the

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methods described in the '939 patent. Applicants respond that a reference must be taken as a whole, and when the '939 patent is considered in its entirety, this reference teaches away from the present invention. Moreover, as discussed above, the legal test for inherency requires that one of ordinary skill in the art recognize the allegedly inherent teaching in the cited prior art reference. This burden has not been satisfied in the present case.

D. Conclusion.

Thus, in view of the reasons discussed extensively above, Applicants submit that the presently-claimed invention is not anticipated by the '939 patent, either expressly or inherently, and respectfully request that the rejection on this basis be withdrawn.

II. Double-Patenting Rejection.

Claims 24-30 stand rejected under the doctrine of obviousness-type double patenting as unpatentable over Claims 1-7 of U.S. Patent No. 6,303,176.

In response to this rejection, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR § 1.321 with respect to U.S. Patent No. 6,303,176. Applicants note that the submission of this terminal disclaimer in no way represents an acquiescence to the outstanding rejection or an acknowledgement that the subject matter of the pending claims is obvious over the cited claims of U.S. Patent No. 6,303,176.

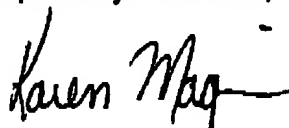
Accordingly, Applicants respectfully submit that the filing of a terminal disclaimer has obviated the outstanding double-patenting rejection, and respectfully request withdrawal of the rejection on this basis.

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III. Conclusion.

The points and concerns raised by the Examiner in the outstanding Final Action having been addressed in full, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested. Should the Examiner have any remaining concerns, it is respectfully requested that the Examiner contacted the undersigned attorney to expedite the allowance of this application.

Respectfully submitted,

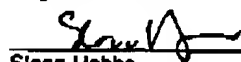


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